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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/858,349	05/15/2001	Daniel Plaksin	87534-2800	2778

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EXAMINER

WESSENDORF, TERESA D

ART UNIT PAPER NUMBER

1639

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/858,349

**Applicant(s)**

PLAKSIN, DANIEL

**Examiner**

T. D. Wessendorf

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20, 34, 36-44, 46 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 11-18, 20, 38, 39 and 41-44 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-10, 19, 34-37, 40 and 46-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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**DETAILED ACTION**

***Status of Claims***

Claims 1-20, 34, 36-44 and 46-47 are pending in the application.

Claims 21-33, 35 and 45 have been cancelled in the 5/15/03 Amendment.

Claims 6-8, 11-18, 20, 38-39 and 41-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b).

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 112***

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for reasons set forth in the office action of 8/10/04.

***Response to Arguments***

The applicant asserts that there is no issue here with a chemical genus and species. Claim 1 recites a charged residue which is exactly what the Lys group is. This language also excludes other residues that are not described in the specification, such as non-charged residues that do not perform as noted in the invention. The skilled artisan knows what similar or equivalent groups can be used instead of Lys, and for these reasons the disclosure is more than sufficient. Furthermore, applicant asserts it is improper to try to restrict applicant's invention to the most preferred embodiment. Also, the rejection does not apply to claims 3-5, 9-10, 19, 34, 36-37, 40 and 46 since those claims are directed to an invention where Lys is present in position 44.

In reply, claim 1 recites a genus i.e., charged residue of the species Lys. While uncharged residues are obviously excluded from the claimed charged residue however, the issue is those charged residues that applicant alleged are equivalent to Lys. There is nothing in the specification that describes or discloses the residues that are equivalent or similar to Lys, at the time of filing. The dependent claims, albeit containing Lys residues are not precluded since as stated in the last Office action, the polypeptide that contains the charged residue is

broad with no definite structure. Applicant is working on a field of immunochemistry where little prediction is possible and that scope of claims should not be unduly extensive in such field where applicability is highly speculative or not explored. Applicant may not preempt an unduly large field by the expedient of making broad prophetic statements in the specification and claims unless the accuracy of such statements is sufficiently supported by well-established chemical principles or by sufficient number of examples. A "written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition, such as by structure, formula [or] chemical name of the claimed subject matter sufficient to distinguish it from other materials".

University of California v. Eli Lilly and Col, 43 USPQ 2d 1398, 1405( 1997), quoting Fiers V. Revel, 25 USPQ 2d 1601m 16106 (Fed. Cir. 1993). See also University of Rochester v. G.D. Searle & Co., 68 USPQ2d 1424 (DC WNY 2003).

***Claim Rejections - 35 USC § 112***

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47, as amended, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons advanced in the last Office action.

***Response to Arguments***

Applicant's argue that the native clone used for exemplifying the invention had a Lys residue at position 44, and not a Gly residue and that there is no artificial mutation or modification made to the clone (page 5, second paragraph). This recitation was added to claim 1 to further distinguish the invention from the cited art (see, last paragraph of specification page 3, second and third paragraphs of specification page 9. The claim language is correct and is not indefinite.

In response, a review of page 5 reveals a different concept than that of claim 1. Claim 1 recites for a natural VH of an antibody. The specification recites for mutations at the VH/VL interface as recited at page 3, last paragraph. Thus, claim 1 is confusing and appears to be at odds with the specification.

***Claim Rejections - 35 USC § 102***

I  
Applicant states that the term "we" was a typographical error and was mentioned in connection with the conducting of various experiments. Although that term was used to refer to the conducted experiments, this has now been changed so that there can be no confusion to whether additional inventors

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participated, which they did not. No new matter has been introduced, so that these changes should be entered. Those errors have now been corrected by amendment. In view of applicant's statement, the rejection of the claims under this statute no longer applies.

***Claim Rejections - 35 USC § 103***

Claims 1-5, 9-10, 19, 34-37, 40 and 46-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over del Rio et al (EP 712863) in view of de Wildt (Protein Engineering) for reasons advanced in the last Office action.

***Response to Arguments***

Applicant submits that it would not been obvious to replace the Gly residue with Lys residue in position 44 of the framework since according to the present invention this does not result in increased affinity as found by de Wildt but in increased stability. De Wildt discloses that the contribution of the Lys residue in CDR3 to specific binding but does not mention or suggest Lys or other charged residues in the framework. All the antibody fragments according to the present invention have a charged residue such as Lys at position 44 of the framework, but only selected ones, with the specific CDR3 sequence, bind antigens of interest. Therefore, the advantage taught by de

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Wildt for increasing affinity by having Lys residue within the CDR3 sequence would not provide any motivation to increase stability by replacing position 44 of the VH/VL interface framework with a Lys residue. Thus, the skilled artisan would not be led to substitute the Lys residue into the framework as taught by the present invention.

In reply, applicant's argument as to the CDR3 being replaced by Lys is not commensurate in scope with at least claim 1. Claim 1 does not recite a CDR3. Whether the function found by applicant i.e., a more stable polypeptide, as opposed to the prior art does not detract from the finding that the compound is known and obvious. The increased affinity would provide the motivation to make the substitution. As it is well known in the art that increased affinity can be achieved if the compound is stable. Applicant is in effect, arguing that a structure suggested by the prior art, and hence potentially in possession of the public, is patentable to them because it also possesses an inherent, but hitherto unknown property, which they claim to have discovered. This is not the law. A patent on such structure would remove the public that which is in the public domain by virtue of its inclusion, or obviousness from the prior art. In re Wiseman 201 USPQ 658. Furthermore, De Wildt clearly teaches substitution at position 44, which is the same position with the



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same residue as the claimed polypeptide. Applicant's arguments are contradictory to the claim, which recites position 44 having the uncharged residue (and the CDR3 being a random residue}. As applicants state above " the skilled artisan knows what similar or equivalent groups can be used instead of Lys..." {Note that de Rio alone, even without De Wildt discloses Lys residue at position 44 (Fig. 1A). See further applicant's statement above in what appears to be a polypeptide, as claimed, being a native VH chain of an antibody.]

No claim is allowed.

#### **Conclusion**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A handwritten signature in black ink, appearing to read 'T.D.' followed by a stylized flourish.

T. D. Wessendorf  
Primary Examiner  
Art Unit 1639

Tdw

May 12, 2005